K083742

FEB 12 2009

510(k) Summary of Safety and Effectiveness

Applicant Name and Address: Collagen Matrix, Inc.
509 Commerce Street
Franklin Lakes, New Jersey 07417

Contact Person: Peggy Hansen, RAC
Sr. Director, Clinical, Regulatory, and QA
Tel: (201) 405-1477
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Date of Summary: December 12, 2008

Device Common Name: Bone Grafting Material

Device Trade Name: Synthetic Mineral - Collagen Bone Graft Matrix

Device Classification Name: Bone Grafting Material, Synthetic
872.3930
LYC
Class II

Predicate Device(s): SynOss™ Synthetic Bone Graft Material
K072397
OsteoGuide™ Anorganic Bone Mineral Products
K043034
FOUNDATION™ Bone Filling Augmentation Material
K040783

Description of the Device

Synthetic Mineral – Collagen Bone Graft Matrix is a composite of synthetic calcium phosphate based granules and type I collagen. The calcium phosphate mineral has an apatite structure similar to that of natural bone. The type I collagen is derived from bovine Achilles tendon. The composite material is a resorbable, porous, osteoconductive bone graft matrix. The product is supplied in granular or block/plug form, and it is sterile, non-pyrogenic, and for single use only.

Intended Use

Synthetic Mineral – Collagen Bone Graft Matrix is intended for use in dental surgery. The products may be used in surgical procedures such as:

- Augmentation or reconstructive treatment of alveolar ridge
- Filling of periodontal defects
- Filling of defects after root resection, apicocectomy, and cystectomy
- Filling of extraction sockets to enhance preservation of the alveolar ridge
- Elevation of maxillary sinus floor

- Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR)
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration

Summary/Comparison of Technical Characteristics

Synthetic Mineral – Collagen Bone Graft Matrix and its predicates have the same technological characteristics. In particular, the Synthetic Mineral – Collagen Bone Graft Matrix and its predicates are the same with respect to intended use, material characterization, and product forms.

Safety

Synthetic Mineral – Collagen Bone Graft Matrix has been evaluated by a number of tests to assess its safety/biocompatibility. The device passed all selected FDA Blue Book Memorandum G95-1and ISO 10993-1 testing for the biological evaluation of medical devices.

Effectiveness

The characteristics of the Synthetic Mineral – Collagen Bone Graft Matrix meet the design requirements for an effective bone grafting material in dental surgery.

Conclusion

The results of the *in vitro* product characterization studies, *in vitro* and *in vivo* biocompatibility studies, show that the Synthetic Mineral – Collagen Bone Graft Matrix is safe and substantially equivalent to OsteoGuide Anorganic Bone Mineral with Collagen.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 2009

Ms. Peggy Hansen
President, Clinical, Regulatory, QA, and Marketing
Collagen Matrix, Incorporated
509 Commerce Street
Franklin Lakes, New Jersey 07417

Re: K083742
Trade/Device Name: Synthetic Mineral – Collagen Bone Graft Matrix
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Codes: LYC, NPM
Dated: December 12, 2008
Received: December 16, 2008

Dear Ms. Hansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083742

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Indications for Use:

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Prescription Use X AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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